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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,300	11/12/2003	Hosheng Tu	GLAUKO.IC3CP1	5751

20995 7590 03/17/2009

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/706,300	TU ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 46-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 46-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 December 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 4, 5, 46-49, 52-54, 56, 57, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 2005/01197371 A1 to Bene.

In the specification and figures, Lynch discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 2, 4, 5, 46, 47, 53, 54, 56, 57, 70, 71, and 72, Lynch discloses an implant 100 with a body comprised of a biocompatible material. The implant may comprise a lumen with an outlet end or distal portion 25 sized and shaped to reside in a physiological outflow pathway such as Schlemm's canal, and an

inlet end or proximal portion 10 sized and shaped to reside in the anterior chamber of the eye, wherein the device permits fluid communication from the anterior chamber to Schlemm's canal (see column 6, lines 50-64, column 9, lines 49-67). Together, the L-shape of the proximal and two distal portions disclosed by Lynch comprise an anchor shape that retains the implant in place.

With regard to applicant's recitation of the body comprising a therapeutic drug, Lynch discloses in the provisional application that, in an embodiment, the apparatus may comprise a reservoir containing a drug or therapeutic agent deliverable to adjacent tissues, but does not disclose that the implant itself comprises a therapeutic agent. However, Bene discloses an ocular implant that may be comprise a therapeutic drug in filter 312 for delivery to the adjacent eye tissue (see at least paragraphs 0059-0061). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent as disclosed by Bene to the implant disclosed by Lynch in order to distribute therapeutic agents to eye tissue, as taught be Bene.

With regard to claims 52 and 55, Bene suggests that the implant may comprise a therapeutic drug that may be in filter 312, which is appended to lumen section 313 (see FIG 30).

With regard to claims 48 and 49, Lynch discloses a method of introducing an implant into the claimed location to facilitate drainage. Lynch fails to specifically disclose the particular drainage method in conjunction with therapeutic drug delivery, but does disclose the drainage and drug delivery as separate procedures. However, Bene discloses an ocular implant for the treatment of glaucoma wherein the implant may

comprise a porous material impregnated with drugs that elute to the surrounding tissue when implanted in the eye (see at least paragraphs 0059-0061). The implant disclosed by Bene allows for long-term, low-dose treatment. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent, as disclosed by Bene, to the glaucoma implant in the method disclosed by Lynch in order to provide a long-term, low dose pharmaceutical treatment for an ocular condition, as taught by Bene.

4. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 2005/01197371 A1 to Bene, further in view of US 7,033,603 to Nelson.

In the specification and figures, the cited prior art suggests the device substantially as claimed by applicant (see rejection above) with the exception of the particular drugs or materials used as bioactive agents in the device. Nelson discloses an implantable hydrogel device that provides drug delivery to various internal locations within a patient. The device disclosed by Nelson may include a growth factor, a gene, TGF-beta, and heparin (see column 7, lines 60-67, column 8, lines 1-22, column 18, lines 50-67, column 17, lines 36-41). It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to provide the implant suggested by the cited prior art with the therapeutic agents disclosed by Nelson in order to provide the desired therapeutic treatment to the patient.

5. Claims 50, 51, and 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 2005/01197371 A1 to Bene, further in view of US 4.521.210 to Wong.

In the specification and figures, the cited prior art suggests the method substantially as claimed by applicant with the exception of placing the implant in contact with a choroid or draining aqueous humor towards the choroid.

With regard to claims 50, 51, 58, 59, 64, 65, 67, 68, and 69, Wong discloses a method for treating an ocular disorder such as glaucoma, comprising the steps of forming an incision in the sclera of the eye, (see column 5, lines 10-15), inserting an implant 40 through the incision into the anterior chamber 32, advancing the implant across a section of the anterior chamber 32 until it comes to rest on stop arm 44 (see column 5, lines 35-47), and allowing the implant to drain aqueous humor from the anterior chamber towards the choroid, which comprises a physiological outflow pathway (see column 5, lines 1-3, 45-53, FIG 4). Wong discloses that the implant disclosed by Wong is positioned to allow fluid to enter the choroidal space while the posterior end 46 of the implant 40 contacts the choroid 22 (see FIG 4). It is the position of the Examiner that the Wong reference reasonably teaches the step of draining aqueous humor towards the choroid. It is the position of the Examiner that, taken together, the

references reasonably suggest the method as claimed by Applicant. One having ordinary skill in the art at the time of invention could have coated the implant disclosed by Lynch with an eluting drug as suggested by Bene, and then inserted the implant in the manner suggested by Lynch, wherein the distal end of the implant contacts the choroid, as suggested by Wong, yielding the predictable result of a drug-eluting implant that drains towards the choroid.

With regard to claims 60 and 66, Lynch discloses the step of draining aqueous through a lumen of the implant (see rejection above).

With regard to claims 61-63, Bene suggests that the implant may comprise a therapeutic drug that may be in filter 312, which is appended to lumen section 313 (see FIG 30, rejection above).

Response to Arguments

6. Applicant's amendment and arguments filed 23 December 2008 have been entered and considered.

7. Applicant's arguments with respect to the 103 rejections over the combinations of Lynch, Wong, and Terry are persuasive, and the rejections have been withdrawn. However, a new grounds of rejection has been presented above over the combination of Lynch, Bene, and Wong.

8. Applicant's arguments with respect to the 103(a) rejections of the claims over the combination of Lynch and Bene are not persuasive.

9. Applicant argues that the Bene reference does not have adequate written support for a drug compound as a part of the ocular implant since Bene discloses only that drugs may be incorporated into the porous material contained within the implant. The Examiner agrees, but interprets the provisional application to fully support the disclosure cited in the instant reference, wherein a therapeutic material may be contained within a porous material within the walls of an implant for delivery to surrounding tissue. As such, it is the position of the Examiner that Bene reasonably suggests the inclusion of a drug in some portion of the ocular implant, thereby rendering the instantly claimed invention unpatentable over the cited art.

10. Applicant further argues that even if the Bene provisional provides an adequate written description, one would not be motivated to combine Bene and Lynch to arrive at the claimed invention. The Examiner respectfully disagrees.

11. Applicant argues that since the Lynch device is contained entirely within the eye, and "should" eliminate complications such as infection, the Lynch reference teaches away from adding a drug, such as an antibiotic, to the Lynch device. Such a disclosure does not amount to a teaching away—only a suggestion that antibiotics might not be needed. Furthermore, the Examiner notes that Bene, even in the provisional application, does not limit the therapeutic drug to an antibiotic. The passage cited by Lynch suggests only that antibiotics might not be needed, not any other drug that might prove to be therapeutic.

12. Applicant argues that since Lynch discloses a "completely hollow" implant, one would not be motivated to add the drug-containing filter disclosed by Bene to the Lynch

apparatus. However, the Examiner notes that Lynch discloses that the apparatus may be "solid, porous, tubular, through-like, fenestrated, or pre-curved" (see column 7, lines 50-54. Accordingly, Lynch teaches that the apparatus may be porous, which leaves open the possibility of inserting the medicated filter disclosed by Bene into the lumen disclosed by Lynch in order to treat and control fluid flow through the lumen.

13. Applicant further argues that the Lynch apparatus teaches using a fluid bolus from a reservoir to introduce a drug in order to eliminate dilution. However, the Examiner is not relying on that particular embodiment disclosed by Lynch in the present rejection. Lynch is relied on to teach the general shape and placement of the device in the claimed method, while Bene is used to teach the desirability of adding a therapeutic drug to an ocular implant that is shaped and implanted in the manner disclosed by Lynch.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
10 March 2009